K000551

MAR 1 6 2000

510(k) Summary
for
Image X-70 Plus Dental X-Ray Unit

1. SPONSOR

AFP Imaging Corporation
250 Clearbrook Road
Elmsford, NY 10523
Contact Person: David Vozick
Telephone: 914-592-6100

Date Prepared: February 17, 2000

2. DEVICE NAME

Proprietary Name:	Image X-70 Plus
Common/Usual Name:	Extraoral X-Ray System
Classification Name:	Extraoral Source X-Ray System

3. PREDICATE DEVICES

AFP Imaging Image X-70 Intraoral X-Ray device	K930761
Gendex Corp 765DC Intraoral X-Ray System with timer	K992610
MDT Diagnostics HDX System	K896024

4. DEVICE DESCRIPTION

The Image X-70 Plus is made up of a self-contained X-ray tube head, a timer and a positioning arm. The system includes a 70 kVp, 8 mA X-Ray tube and 0.7 x 0.7 mm focal spot which assures high quality, sharp, well defined diagnostic X-rays.

The Image X-70 Plus X-ray tube head contains a high voltage transformer, a stationary anode X-ray tube, and a fixed cone that screws into the tube head which acts as a beam-limiting device

The positioner arm provides firm control for positioning the head for all procedures. The arm is easily adjusted for variable weights and arm lengths. The Image X-70 Plus timer may be mounted outside the exam room. The timer includes visual and audible signals to indicate the exposure has been made. The timer safety limits exposures over 3.0 seconds

5. INTENDED USE

The Image X-70 Plus Dental X-Ray Unit is intended for use an extraoral source X-Ray system for dental radiographic examination and diagnosis of diseases of the teeth.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The AFP Image X-70 Plus Dental X-Ray System is substantially equivalent to the AFP Imaging Image X-70 Intraoral X-Ray device, the Gendex Corp 765DC Intraoral X-Ray System with timer, and MDT Diagnostics HDX System. All of the systems provide an extraoral source X-ray system for dental radiographic examination and diagnosis of diseases of the teeth.

The AFP Imaging Image X-70 Plus and the Image X-70 have essentially identical performance characteristics. The proposed and predicate devices deliver a standard dental film that can be viewed by the dentist. The exposure times are similar for the proposed and predicate devices.

7. PERFORMANCE TESTING

The modifications made to the Image X-70 Dental X-Ray unit were validated and found not to affect the intended use or technological characteristics of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 6 2000

AFP Imaging Corporation
C/O Mary McNamara-Cullinane, RAC
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K000551
Image X-70 Plus Dental X-Ray Unit
Dated: February 17, 2000
Received: February 18, 2000
Regulatory class: II
21 CFR 872.1800/Procode: 90 EHD

Dear Ms. McNamara:

We have reviewed your premarket notification submission and have found this device to be exempt from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (Act). The Act was amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA). Section 206 of FDAMA added section 510(l) to the Act. This provision became effective on February 19, 1998. Section 510(l) states that a report under section 510(k) is not required for class I devices unless the class I device is for a use which is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury. FDA does not believe that the device for which you submitted a report under section 510(k) is of substantial importance in preventing impairment of human health or that it presents a potential unreasonable risk of illness or injury. Therefore, you may immediately begin marketing this device as described in your premarket notification, subject to any other applicable requirements of the Act.

FDA published a Federal Register notice on January 14, 2000 (Volume 65 Number 10) identifying your device type as exempt from premarket notification. This regulation became effective February 14, 2000. Your device's product code, classification regulation name and regulatory class are shown above. When listing your device with FDA, please use this product code. We suggest that you review the above referenced classification regulation since it may grant other exemptions from certain general controls of the Act. We also suggest you review the section entitled "Limitation on Exemptions" found in the January 14, 2000, Federal Register notice to determine whether or not any changes to your device will meet the exemption criteria. This Federal Register notice may be accessed on the World Wide Web at: www.fda.gov/OHRMS/DOCKETS/98fr/011400a.pdf or obtained by facsimile from the Facts On Demand System of the Division of Small Manufacturers Assistance at (800) 899-0381 or (301) 827-0111.

If you have any questions regarding this letter, please contact the 510(k) Staff at (301) 594-1190.

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known):

Device Name: AFP Imaging Corporation Image X-70 Plus Dental X-Ray Unit

Indications For Use:

The Image X-70 Plus Dental X-Ray Unit is intended for use as an extraoral source X-Ray system for dental radiographic examination and diagnosis of diseases of the teeth.

(PLEASE DO NOT WRITE BELOW THIS LINE -
CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K000551

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)